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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,635	08/21/98	MELTZER	P 4239-50420

HM12/0103

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EXAMINER	
BASI,N	
ART UNIT	**PAPER NUMBER**
1646	13

DATE MAILED: 01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/125,635	Meltzer et al
Examiner	**Group Art Unit**
Nirmal. S. Basi	1646

☒ Responsive to communication(s) filed on *Oct 6, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *12-65* is/are pending in the application.

Of the above, claim(s) *12-54* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *55-65* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *12-65* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on *Aug 21, 1998* is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Amendment and response to Restriction Requirement filed 10-06-00 (paper number 12) has been entered.

Election/Restriction

2. Applicant's election with traverse of Group I (Claims 55-65), in Paper No. 12 (8-30-00), is acknowledged. The traversal is on the ground(s) that the inventive concept of an AIBI gene was disclosed in Guan et al., Cancer Research 56:3446-3450 (August 1, 1996), thereby negating a technical relationship between Groups I-VIII. The Guan et al. reference contains additional authors than those of instant application, and without a signed declaration showing that the additional authors did not make an inventive contribution to the subject matter of the claimed invention, of instant application, the lack of unity is maintained. The lack of unity may be overcome either by a showing under 37 CFR 1.132 that any invention disclosed in instant application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. In the event the Applicant provides a declaration that instant invention was not the invention "by another," then the claims of Group II (polypeptide encoded by Group I) and Group IV (method of identifying a candidate compound which inhibits estrogen (ER) receptor-dependent transcription comprising contacting the compound with the AIBI polypeptide of claim 12) will be rejoined. The claimed if rejoined in the afore mentioned manner will, therefore, include the product, method of making the product (none is claimed) and first method of use of the product.

Specification

3. This application is informal in the arrangement of the specification.

A) Cross-References to Related Applications. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

B) Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). Applicant has used the heading "FIGURES".

The drawings objected to because each Figure must described separately in the Brief Description of the Drawings. For example: a) Figure 1 should be labeled as Figure 1A and 1B or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1), the description in "FIGURES" indicates Fig. 1A and Fig. 1B, but Fig 1 is represented as Figure 1 in the drawings. Figure 2 must be must described separately in the Brief Description of the Drawings as Figure 2A and 2B. Figure 5 is contained on two separate sheets and must be labeled as Figure 5A and Figure 5B and described separately in the Brief Description of the Drawings. Figure 6 is contained on two separate sheets and must be labeled as Figure 6A and Figure 6B and described separately in the Brief Description of the Drawings. Sequences in Figures 1, 5 and 6 must be identified by their corresponding SEQ ID NO:. in the Brief Description of the Drawings

Appropriate correction is required.

4. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figure 1, 5 and 6 must be identified by their corresponding SEQ ID NO:. Compliance with sequence rules is required.

Claim Objection

5. Claims 55-65 objected to as being in improper dependent form because a claim cannot depend on a non elected claim, directly or indirectly. Claims 55-65 depend, directly or indirectly, on non elected claim 12. It is suggested, to overcome the objection, claims 55-65 be rewritten to include all of the limitations of the base claim and any intervening claims. Further claims 57-63 must refer to sequences as SEQ ID NO: and not SEQ. I.D. NO..

Claim Rejection, 35 U.S.C. 112, first paragraph

6. Claims 55-56, 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotide:

a) encoding A1B1 polypeptide

b) encoding the polypeptide comprising SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4 and SEQ ID NO:8

c) encoding the A1B1 polypeptide which hybridizes to the DNA having the sequence of SEQ ID NO:1

d) encoding the A1B1 polypeptide having 50% sequence identity to SEQ ID NO:1

e) comprising SEQ ID NO:1 and degenerate variants of SEQ ID NO:1

The claims are further directed to cell comprising the DNA encoding the human A1B1 polypeptide.

The claims, as written, encompass polynucleotides which vary substantially in length and also in nucleotide composition. The instant disclosure of a polynucleotide of SEQ ID NOs:1 does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes, nucleic acids encoding chimeric proteins or fusion proteins and variants. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The specification proposes to discover other members of the genus by using hybridization (pages 7). There is no description, however, of the sites

at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed. No identifying characteristic or property of the instant polynucleotides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the inability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Accordingly, the specification does not provide a written description of the polynucleotides of the invention (full-length genes, nucleic acids encoding chimeric proteins or fusion proteins and variants, disclosed above), and further the claims do not provide written description of cells comprising said non-native polynucleotides.

Claim Rejection, 35 U.S.C. 112

7. Claims 55-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 55 and 56 are indefinite because the name A1B1 has not been defined in the claims and specification so as to allow the metes and bounds of the claims to be determined. The name A1B1 polypeptide is not an art accepted term and does not provide any structural or functional properties of the polypeptide. It is suggested that A1B1 polypeptide be identified by its SEQ ID NO:.

Claims 57-65 are rejected for depending upon an indefinite base (or intermediate) claim and fail to resolve the issues raised above.

Claim Rejections, 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 55- 56, 61 and 64-65 are rejected under 35 U.S.C. 102(a) as being anticipated by Guan et al (IDS , Cancer Research 56:3446-3450 (August 1, 1996)). Guan et al disclose a

substantially pure DNA comprising a sequence encoding a human A1B1 polypeptide, said DNA is contained in a cell, is capable of hybridization to the polynucleotide of SEQ ID NO:1, contains regulatory sequences thereby meeting the limitations of claims 55-56, 61 and 64-65, absent evidence to the contrary.

11 Claims 55- 56, 61 and 64-65 are rejected under 35 U.S.C. 102(a) as being anticipated by Torchia et al (IDS , Nature Vol. 387, 12 June, 1997). Torchia et al disclose (see methods, pages 683-684 and attached sequence comparison) a substantially pure DNA comprising a sequence encoding a human A1B1 polypeptide, said DNA is contained in a cell, is capable of hybridization to the polynucleotide of SEQ ID NO:1, contains regulatory sequences and has 40.5% query match and 78.0% sequence identity to the DNA of SEQ ID NO:1, thereby meeting the limitations of claims 55-56, 61 and 64-65, absent evidence to the contrary.

No claim is allowed

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
January 1, 2001

Yvonne Eyler

YVONNE EYLER, PH.D
PRIMARY EXAMINER